

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ADAMS RESPIRATORY
THERAPEUTICS, INC., ADAMS
RESPIRATORY OPERATIONS, INC.
AND ADAMS RESPIRATORY
PRODUCTS, INC.,

Plaintiffs,

v.

Case No. 1:07-CV-993

PERRIGO COMPANY, L. PERRIGO
COMPANY AND PERRIGO RESEARCH
AND DEVELOPMENT COMPANY,

HON. GORDON J. QUIST

Defendants.

OPINION

Plaintiffs (collectively, “Adams”) have filed a Motion to Strike Defendants’ Fifth and Sixth Defenses and to Dismiss Counterclaims V and V (sic, VI), or in the Alternative for a More Definite Statement. (Docket no. 86.) Defendants’ (collectively, “Perrigo’s”) fifth defense alleges that Adams’s patent, U. S. Patent No. 6,372,252 (the “‘252 patent”), is unenforceable by virtue of Adams’s reputed inequitable conduct before the Patent Office and subsequent purported patent misuse. The basis for Perrigo’s inequitable conduct allegation is its averment that Adams intentionally withheld relevant prior art during the ‘252 patent prosecution. This prior art includes “[Mutual’s] 600 mg extended-release guaifenesin tablets,” and the “extended-release, single-ingredient guaifenesin products” sold more than a year before Adams’s ‘252 patent application and manufactured or distributed by the recipients of a letter the FDA posted after it approved Adams’s New Drug Application (NDA). The letter warned each recipient it must cease manufacturing its

“unapproved single ingredient guaifenesin extended release products no later than May 21, 2003.” Adams contends Perrigo’s First Amended Answer (docket no. 68) does not identify the alleged prior art or its materiality with the particularity required of fraud allegations by Fed. R. Civ. P. 9(b).

The basis for Perrigo’s patent misuse allegation is its averment that Adams knew the ‘252 patent was invalid when it filed suit. Perrigo claims Adams knew this because of its inequitable conduct, the “information in Perrigo R&D’s paragraph IV certification[,] and facts made known to Adams during the *Mutual* Litigation.” Adams counters that Perrigo’s charge of patent misuse fails to satisfy Rule 9(b)’s particularity requirement because it relies in part on Perrigo’s purportedly insufficient allegation of inequitable conduct and it avers no facts suggesting Adams actually knew the ‘252 patent was invalid. Adams also contends that even if Perrigo has alleged sufficient facts, Perrigo relies upon extrinsic evidence to supply them, contrary to Rule 9(b)’s requirement that particularity be satisfied by the pleading itself.

I. Analysis

Inequitable conduct, while a broader concept than fraud, must be pled with particularity. Fed. R. Civ. P. 9(b), *Ferguson Beauregard/Logic Controls, Inc. v. Mega Sys. LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003).

A. Reliance Upon Extrinsic Evidence

The first question is whether the Court may look to extrinsic matters to determine whether a party has met the particularity requirement.

A documentary exhibit to a pleading is part of the pleading *for all purposes*. Fed. R. Civ. P. 10(c) (emphasis added). “All purposes” includes the satisfaction of Rule 9(b)’s particularity requirement. Furthermore, the extrinsic evidence the Court may consider is not limited to exhibits to the pleadings. “[D]ocuments incorporated into the complaint by reference, and matters of which

a court may take judicial notice” are also considered part of the pleading. *Tellabs, Inc., v. Makor Issues & Rights, LTD.*, 551 U.S. 308, 127 S. Ct. 2499, 2509 (2007)¹. This includes public records as well. *Amini v. Oberlin Coll.*, 259 F.3d 493, 502-03 (6th Cir. 2001) (holding that the district court’s failure to consider information contained in EEOC filing was error because “[i]n determining whether to grant a Rule 12(b)(6) motion, . . . matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint” may be considered). *Tellabs* and *Amini* make clear that exhibits to the complaint are not the only external sources regarded as part of the pleading.

That numerous sources extrinsic to the pleadings may be regarded as part of the pleadings, not only for consideration of a Rule 12(b)(6) motion, but also for consideration of the particularity requirement of Rule 9(b), is demonstrated by *Tellabs* in discussing the interplay between Rules 9(b) and the Public Securities Litigation Reform Act pleading requirements. 15 U.S.C. § 78u-4(b)(1), (2). Among other things, *Tellabs* addressed whether the Court could consider extrinsic sources to determine whether the plaintiffs’ amended complaint satisfied Rule 9(b)’s particularity requirement. The Court held that extrinsic sources *must be* considered:

. . . courts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice. The inquiry, as several Courts of Appeals have recognized, is whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.

Tellabs, 551 U.S. 308, 127 S. Ct. at 2509 (citations omitted).

¹ Pinpoint cites to volume 551 of the U.S. Reports were not available when this Memorandum Opinion & Order was drafted.

Adams acknowledges that in *Commercial Money Center, Inc. v. Illinois Union Insurance Co.*, 508 F.3d 327, 336 (6th Cir. 2007), the Sixth Circuit held that “a court may consider matters of public record in deciding a motion to dismiss without converting the motion to one for summary judgment.” However, Adams insists that the public records relied on in *Commercial Money Center* did not convert a motion to dismiss into one for summary judgment only because those public records were “not offered to establish any disputed facts.” *Id.* That is dicta. The cases in which courts *have* held that consideration of extrinsic sources to evaluate a motion to dismiss required converting the motion into one for summary judgment mischaracterize the analysis of a motion to dismiss. A court examining a motion to dismiss assumes the truth of the non-moving party’s allegations. *Tellabs*, 551 U.S. 308, 127 S. Ct. at 2509. At issue is not the verity of disputed facts, but whether the alleged facts, if true, establish a cognizable theory of relief. Whether consideration of extrinsic sources requires converting a motion to dismiss into one for summary judgment depends not on whether the extrinsic sources contain disputed facts, but on whether the extrinsic sources are of the kinds which may be considered in examining a motion to dismiss. For instance, if the Court considers an affidavit attached to a motion to dismiss, the Court must convert the motion into one for summary judgment. However, if that affidavit is attached to the pleadings, the Court can consider it without converting the motion, regardless of whether the information in the affidavit is disputed.

The extrinsic sources at issue in this motion are matters of public record. Most are also referred to in Perrigo’s First Amended Answer and are central to Perrigo’s defense. The Court may consider these sources, even those containing disputed facts, in its analysis of a motion to strike or dismiss a portion of an answer for its alleged failure to satisfy the particularity requirement of Rule 9(b).

B. Rule 9(b) Particularity Requirement

Adams contends Perrigo has insufficiently pled its allegation of inequitable conduct because it did not identify allegedly relevant prior art and provided no factual basis for materiality. This argument is unpersuasive. Records of prior suits, FDA warning letters, and SEC filings are matters of public record. As explained above, they may be considered, even if not referenced in the pleadings themselves. Mutual's product was specifically identified by name in the prior litigation. The FDA warning letters enable Adams, at least, to identify the allegedly material prior art based on their pharmaceutical description ("single ingredient guaifenesin extended release products"), manufacturer, and time and country of sale. Adams's SEC filing demonstrates Adams was able to make this identification. Perrigo's answer alleges materiality as well; it states that Adams knew the prior art was sold in the United States more than a year before the '252 patent application. The materiality is further illustrated by Perrigo's paragraph IV notice letter to Adams and the record of Adams's prior suit with Mutual. Accordingly, Perrigo's fifth and sixth defenses will not be stricken.

C. Perrigo's Fifth and Sixth Counterclaims

Adams' motion, in essence, required this Court to examine whether Perrigo's claims of inequitable conduct and misuse put Adams on sufficient notice as required by Rule 9(b). It is this Court's conclusion that Perrigo's allegations are sufficient. Furthermore, although patent misuse is an affirmative defense, it may also form the basis for a declaratory judgment counterclaim of unenforceability. Therefore, Adams' Motion to Strike will be denied.

A separate Order will issue.

Dated: January 26, 2009

/s/ Gordon J. Quist
GORDON J. QUIST
UNITED STATES DISTRICT JUDGE